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ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/662,006	SULLIVAN ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *56 and 76-187* is/are pending in the application.

4a) Of the above claim(s) *175-183* is/are withdrawn from consideration.

5)☒ Claim(s) *56 and 187* is/are allowed.

6)☒ Claim(s) *76-97,99-118,120-134,139-141,145,147,149-174 and 184-186* is/are rejected.

7)☒ Claim(s) *98,114,119,142,146,148 and 152* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 April 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/15/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This is a final Office action. Any new rejections were necessitated by the applicants' changes to the claims.

Election/Restrictions

Newly submitted claims 175-183 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The newly submitted claims are drawn to an apparatus or method including a processor for or a step of processing signals to differentiate between signals due to physiological parameters and signals due to extraneous movement by correlating the signals between the two sensors. Previously presented embodiments are drawn to an apparatus or method including a processor or step of (1) determining a pulse wave velocity in response to a physiological signal time difference between a first and a second sensor (2) measuring a pulse wave travel time between two sensors and (3) comparing signals from the two sensors to determine locations of the sensors on the patient. An embodiment in which physiological parameters an extraneous movement signals are differentiated was not previously presented.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 175-183 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

Claim 114 is objected to because of the following informalities: on line 1 of claim 114, "claim 107" should be replace with "claim 112". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

Claims 135-138, 143, 144, 150 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention:

The specification lacks ample support for a processor for or step of extracting signals due to cardiac activity of a patient by selectively omitting signals from sensors remote from the patient's extremities as claimed in claims 135-138 (see independent claim 135), 143, and 144.

Similarly, the specification fails to provide ample support for an apparatus having at least three sensors at at least three different parts of the patient's body and a processor that determines pulse wave velocity in response to the time difference between signals from at least three sensors, as claimed in claims 150, 154-158, 161, 164-174. While the specification states, "measurement and characterization of the pulse-wave velocity (PWV) or, alternately, the pulse-wave ravel time (PWTT), inherently requires more than one measurement location. Thus, plural sensors are required for

measurements in different locations" (pp. 22-23 of the instant specification) and provides an example in which pulse wave travel time is determined between two locations along an arm (Fig. 8, p. 23 of the instant specification), the applicants have failed to disclose using three sensors or a processor that determines pulse wave velocity in response to the time difference between signals from at least three sensors.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 76, 77, 82-84, 86, and 88 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 4,686,999. Snyder teaches a method for passively monitoring the physiology of a patient in a vibration environment comprising the steps of coupling a polarized polymer film sensor with piezoelectric properties with a patient and sensing and converting the mechanical activity of the patient with the sensor (col. 5, lines 46-55). Signals corresponding to the physiology of the patient are extracted and signals associated with a selected physiological parameter of the patient are separated (col. 5, lines 56-61). A signal representative of the selected physiological parameter of the patient is outputted (col. 5, lines 61-66).

Regarding claim 77, the sensor comprises a polyvinylidene fluoride film (Col. 5, lines 51-52).

Regarding claim 82, the sensor is disposed along a patient supporting surface (col. 5, lines 50-52).

Regarding claim 83, the sensor may be placed on the patient (col. 12, line 62-col. 13, line 2).

Regarding claim 84, the sensor is encased in a protective covering, such as the mattress (col. 5, lines 50-52).

Regarding claim 86, the sensing step includes sensing mechanical activity of the patient through at least one layer of bedding (col. 5, lines 47-52 of Snyder), wherein bedding includes the bed itself and its furniture ("bedding" *Webster's Revised Unabridged Dictionary*).

Regarding claim 88, the film is disposed within a pad (col. 5, lines 44-52).

Claims 89-91, 96,103, 106, 107, 108, 121-123,126, 139, 145, 151, and 153 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 4,245,648 to Trimmer et al. Trimmer teaches a method wherein a first sensor 1 and a second sensor 2 are coupled with the patient (col. 2, line 65-col. 3, line 5) and physiological parameters of the patient and conditions of the environment around the patient are sensed with both the first and second sensors (col.4, lines 36-55), wherein any sensor will inherently pick up some environmental signals and noise during usage. The parameters and environment conditions are converted into signals (col. 7, lines 22-27) and a processor 30 correlates the signals from the first and second sensors 1 and 2 to extract signals associated with the physiology of the patient (col. 4, line 53-col. 6, line 14).

Regarding claims 90 and 91, the first and second sensors 1 and 2 comprise passive electromechanical transducers for sensing mechanical activity of the patient's body (col. 2, lines 49-50). With further regard to claim 91, the sensors are piezoelectric sensors.

Regarding claims 106 and 121, the sensing step comprises sensing mechanical activity of the patient, such as a pulse pressure wave, which is associated with cardiac and respiratory functions (col. 2, lines 39-50; col. 22, line 66-col. 3, line 54).

Regarding claims 151 and 153, the processor 30 determines pulse wave travel time (PPWTT) in response to the time difference between corresponding signals form the sensors 1 and 2 (col. 4, lines 53-61; col. 5, lines 21-30) and converts the PPWTT into signals corresponding to blood pressure data (col. 6, line 4-col. 7, line 5). With further regard to claim 153, the blood pressure data comprises signals corresponding to systolic and diastolic blood pressure (col. 6, lines 8-11; col. 6, line 63-col. 7, line 5).

Claim 89-91, 96, 99-101, 103, 106-108, 112, 115, 122, 123, 125-133, 139, and 145 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 5,964,720 to Pelz. Pelz discloses monitoring the physiology of a patient wherein a plurality of sensors 31 are disposed along a patient supporting surface and coupled with the patient (figs. 3-5; col. 5, lines 25-36 of Pelz), physiological parameters of the patient and conditions of the environment around the patient are sensed with each sensor 31 (col. 5, lines 52-59 of Pelz) and converted into signals, and the signals are correlated to extract signals associated with the physiology of the patient (col. 6, lines 8-40; fig. 11 of Pelz).

Regarding claims 96,100, and 132, the sensors 31 will inherently sense some noise and vibration from the environment around the patient. Additionally, a separate sensor may sense noise and vibration from the environment around the patient (col. 6, lines 56-65 of Pelz).

Regarding claims 101 and 128, the sensors 31 sense mechanical activity of the patient (col. 4, lines 24-44 of Pelz).

Regarding claims 106 and 129-131, the sensed mechanical activity may be cardiac or respiratory signals (Col. 3, lines 22-65; col. 5, lines 1-10; col. 5, line 60-col. 6, line 43 of Pelz).

Regarding claims 112, 122, 123, 125, and 126, a monitor, shown in fig. 1 and 2 as being part of computer 13, communicates with a processor 3 for displaying the physiological data (col. 3, lines 49-67 of Pelz). With further regard to claim 125, the patient supporting may be a bed (col. 4, lines 1-10 of Pelz), an item of furniture, a cushion, a seat back (col. 4, lines 54-64 of Pelz) or seat (fig. 4 of Pelz). With further regard to claim 126 the sensors are configured to measure pulse wave travel time (Col. 6, line 20 of Pelz).

Regarding claim 127, the processor correlates the digital signals between the plurality of sensors to attenuate signals caused by ambient conditions (col. 6, lines 56-65 of Pelz).

Claims 107, 108, 112, 115-117, 120-123, 125-132, 145, and 184 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,853,005 to Scanlon, herein referred to as Scanlon '005. Scanlon '005 describes an apparatus comprising at

least two sensors (col. 11, lines 1-10, col. 12, lines 11-25 of Scanlon '005), each sensor being capable of passively sensing physiological parameters of a patient at a different location on the patient's body and vibration from an environment around the patient, and a processor for processing the signals from the sensor to extract signals associated with the physiologic of the patient by correlating signals between sensors (col. 11, lines 7-10; col. 12, lines 26-29 of Scanlon '005). The processor 15 may be the circuitry disclosed in US Patent No. 5,515,865 to Scanlon, herein referred to as Scanlon '865, which is incorporated by reference into the disclosure of Scanlon '005 (col. 5, lines 47-53; col. 11, lines 20-27 of Scanlon '005). The circuitry disclosed in Scanlon '865 may include a digital signal processor (col. 4, lines 50-56 of Scanlon '865) an A/D converter would necessarily be included in order to allow the digital signal processor to process the signals.

Regarding claims 108,123, and 127-132, the sensors comprise electromechanical transducers for sensing mechanical activity of the patient's body and producing electrical signals in response thereto (col. 5, lines 20-27; col. 6, lines 18-34 of Scanlon '005). With further regard to claims 127-132, and 134 the processor correlates the signals between the sensors to attenuate signal caused by ambient conditions, particularly environmental vibration signals (col.11, lines 7-10; col. 13, lines 26-29 of Scanlon '005).

Regarding claims 112, 122, 123, 125, and 126 a monitor communicates with the processor 15 for displaying the physiological data in real time (col. 6, lines 2-5 of Scanlon '005). As to the language "configured to measure pulse wave travel time" in

claim 126, the sensors disclosed by Scanlon '005 are capable of sensing the pulse wave of a patient at plural locations on a patient's body for the determination of pulse wave travel time between the locations (col. 7, lines 54-60 of Scanlon '005).

Regarding claims 115, 116, 122, 123, 125, and 126, the sensors may be disposed along a patient-supporting surface (col. 12, lines 18-25, fig. 6 of Scanlon '005). With further regard to claim 116, the patient-supporting surface may be a medical transport (col. 7, line 65-col. 8, line 5 of Scanlon '005). With further regard to claim 125, the patient-supporting surface may be a stretcher or litter, a gurney (col. 7, line 65-col. 8, line 5 of Scanlon '005), an operating table (col. 8, lines 23-25), a bed, wherein a bed is an item of furniture (col. 9, lines 5-10 of Scanlon '005), a cushion (col. 9, lines 11-19; col. 15, lines 42-45 of Scanlon '005), a seat, or a seat back (col. 15, lines 42-45 of Scanlon '005).

Regarding claim 117, the sensors may be disposed in hospital bedding (col. 7, line 65-col. 8, line 5; col. 8, lines 29-34 of Scanlon '005), where bedding includes "a bed and its furniture" or "bedclothes", ("bedding" *Webster's Revised Unabridged Dictionary*).

Regarding claim 120, a pad 12 incorporates the sensors and has an interface within the pad formed of gel, water (col. 5, lines 6-15 of Scanlon '005), foam (col. 6, lines 50-54 of Scanlon '005), rubber, or plastic (col. 4, lines 57-61 of Scanlon '005).

Regarding claims 121, 129-131, 139 the processor 15 may extract signals associated with cardiac and respiratory activity of the patient (col. 12, lines 30-42 of Scanlon '005).

Regarding claims 145 and 184, the description of the apparatus itself inherently discloses the method of using the apparatus (Col. 12, lines 11-37 of Scanlon '005). With further regard to claim 184, the sensor may be used in a helicopter environment (col. 10, lines 59-66 of Scanlon '005)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 76-88, 109-111, 124, 133, 134, 140, 141, and 185 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scanlon '005, as applied to claims 107, 108, 112, 115-117, 120-123, 125-132, 145, and 184 above, and further in view of Snyder. Scanlon discloses that the sensor 14 may be any type of suitable pressure and motion sensing type of sensor (col. 5, lines 23-27 of Scanlon '005) but fails to specifically recite polyvinylidene fluoride (PVDF) film. However, Snyder shows that the polarized piezoelectric film of polyvinylidene fluoride is a pressure and motion sensing type of sensor suitable for placement in a mattress and for sensing physiological and movement signals from a patient (Col. 5, lines 49-61 of Snyder). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use PVDF as the sensor of Scanlon '005, since Scanlon discloses using any suitable pressure and motion sensor, and Snyder descries PVDF as such a suitable sensor.

With further regard to claim 78, the vibration environment comprises a medical transport (col. 7, line 65-col. 8, line 5 of Scanlon '005).

With further regard to claims 79 and 81, the vibration environment comprises a helicopter or an ambulance (col. 10, lines 59-66 of Scanlon '005).

With further regard to claim 80, the parameter may be respiratory rate or pulse rate (col. 16, lines 1-2 of Scanlon '005).

With further regard to claims 85 and 86, the sensing step may include sensing mechanical activity of the patient through one or more layers of clothing, as shown in figure 23 of Scanlon '005, or through bedding (col. 7, line 65-col. 8, line 5; col. 8, lines 29-34 of Scanlon '005), where bedding includes "a bed and its furniture" or "bedclothes", ("bedding" *Webster's Revised Unabridged Dictionary*).

Claims 76, 77, 82, 84, 87, 88, 92, 93, 102, 109-111, 124, 133, 140, 141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pelz, as applied to claims 89-91, 96, 99-101, 103, 106-108, 112, 115, 122, 123, 125-133, 139, and 145 above, and further in view of US Patent No. 5,479,932 to Higgins et al. Pelz teaches various embodiments of the sensors, where the sensor may be a flat piezoelectric element or film (col. 4, lines 26-44 of Pelz). However, Higgins teaches that PVDF (polyvinylidene fluoride) film is a type of polarized, polymeric piezoelectric material (col. 5, lines 39-60) suitable for sensing physiological parameters. Therefore, it would have been obvious to use PVDF as the sensor of Pelz, since Pelz teaches using a piezoelectric film, and Higgins teaches that PVDF is a suitable piezoelectric film.

Regarding claim 87, the sensors may be arranged in an array (Fig. 3 of Pelz).

Claims 92, 93,104, 105, 109, 110, 124, 140, 141, 147, 149, 159, 160, 162, and 163 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trimmer et al., as applied to claims 89-91, 96,103, 106-108, 121-123, 126, 139, 145, 151, and 153 above, and further in view of Snyder. Trimmer teaches that the sensors may be piezoelectric sensors (col. 2, lines 49-50 of Trimmer et al.) but fails to teach using a polarized polymer film with piezoelectric properties. However, Snyder shows that a film of polyvinylidene fluoride (PVDF) is a polarized piezoelectric film suitable for sensing physiological signals in a patient (col. 5, lines 49-61 of Snyder). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use PVDF as the sensor of Trimmer et al. since Trimmer describes using a piezoelectric sensor, and since Snyder shows that PVDF is such a piezoelectric sensor.

Regarding claims 147, 149, 159, and 160 the processor determines pulse wave velocity in response to a time difference between corresponding signals from the sensors and converts the pulse wave velocity into signals corresponding to blood pressure data (col. 4, lines 31-34; col. 6, lines 44-50; col. 6, line 63-col. 7, line 5 of Trimmer et al.) With further regard to claims 149 and 160, the blood pressure data corresponds to systolic and diastolic blood pressure data.

Regarding claims 160, 162, and 163, the processor determines pulse wave travel time in response to the time difference between corresponding signals from the sensors and converts the pulse wave travel time into signals corresponding to blood pressure data (col. 4, lines 20-24 and 45-61; col. 6, lines 4-8; col. 6, line 15-col. 7, line 5 of Trimmer et al.)

Claims 94 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scanlon '005 as applied to claims 107, 108, 112, 115-117, 120-123, 125-132, 145, and 184 above in view of Trimmer. Scanlon '005 teaches a plurality of sensors coupled to a patient where the sensors sense physiological parameters of the patient and the conditions of the environment around the patient (col. 7, lines 42-53; col. 13, lines 1-11; figs. 3 and 18 of Scanlon '005). An interface is disposed between the film and the patient (col. 5, lines 6-27 of Scanlon '005). Scanlon '005 discloses that the data from each individual transducer can be used to assess time-of arrival at various positions in the body (col. 7, lines 54-60 of Scanlon '005) and that such a plurality of sensors may be used to determine blood pressure (col. 14, lines 4-14 of Scanlon '005) but fails to describe the processing steps for doing so. However, Trimmer teaches a method of determining blood pressure and pulse wave travel time using two piezoelectric sensors 1 and 2 by converting the sensed physiological parameters and environment conditions into signals (col. 7, lines 22-29 of Trimmer), correlating the signals from the first and second sensors (col. 4, lines 20-25 and 36-62 of Trimmer), and using the correlation to extract signals associated with the physiology of the patient (col. 6, line 4-col.7, line 5 of Trimmer). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the method of Trimmer with that of Scanlon '005 since Scanlon '005 discloses determining blood pressure and pulse wave transit time, and Trimmer teaches an appropriate process of doing so.

Regarding claim 95, the interface may be gel, water (col. 5, lines 6-15 of Scanlon '005), foam (col. 6, lines 50-54 of Scanlon '005), rubber, or plastic (col. 4, lines 57-61 of Scanlon '005).

Claims 97 and 118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pelz, as applied to claims 89-91, 96, 99-101, 103, 106-108, 112, 115, 122, 123, 125-133, 139, and 145 above, and further in view of Scanlon '005. Pelz discloses using a third sensor may be used for sensing and converting into signals the environmental conditions without the physiological parameters of the patient (col. 6, lines 56-65 of Pelz) and subtracting the third sensor signal from the main signals. Pelz fails to provide detail as to the third sensor's detail. However, Scanlon '005 teaches a method of separating environmental noise from physiological signals by placing a reference sensor 132 in a location isolated form the patient (col. 12, lines 18-22 of Scanlon '005). Therefore, it would have been obvious to one of ordinary skill in the art to combine the method of Scanlon '005 with that of Pelz, since Pelz teaches reducing environmental interference in physiological signals and Scanlon '005 discloses appropriate steps for facilitating such a method.

Claims 113 and 114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scanlon '005 (which incorporates Scanlon "865 by reference), as applied to claims 107, 108, 112, 115-117, 120-123, 125-132, 145, and 184 above, and further in view of US Patent No. 5,724,025 to Tavori. Scanlon '005 and Scanlon '865 are silent as to the type of connection between the converter and the processor. Scanlon '005 shows the connection between the monitor and processor as being a wired connection in figure 1.

However, Tavori shows that data communication may be conducted equivalently using either a wired connection or a wireless connection (Col. 5, lines 39-64 of Tavori). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a wireless communication between the converter and the processor, since Scanlon '005 and Scanlon '865, which is incorporated by reference into the disclosure of Scanlon '005, discloses data communication between the converter and the processor, and Tavori shows that wireless communication is an appropriate means of data communication. Similarly, it would have been obvious to use wireless communication between the monitor and the processor of Scanlon '005, since Scanlon '005 teaches a wired connection between the two elements, and Tavori teaches that a wired connection and a wireless connection are functionally equivalent in data communication.

Claim 184 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pelz, as applied to claims 89-91, 96, 99-101, 103, 106-108, 112, 115, 122, 123, 125-133, 139, and 145 above. Pelz discloses monitoring the physiology of a patient in a noisy environment such as an airplane or a car (Col. 6, lines 56-65 of Pelz, but fails to specify such a method in a helicopter. The applicants have not disclosed that performing the method in a helicopter environment over any other noisy environment solves any stated problem or is for any particular purpose. Moreover, it appears that the method would work equally well in any noise environment. Accordingly, the performance of the method in a helicopter environment is deemed to be design consideration which fails to patentably distinguish over the prior art of Pelz.

Claim 185 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pelz, as applied to claim 184 above, and further in view of Higgins. Pelz teaches various embodiments of the sensors, where the sensor may be a flat piezoelectric element or film (col. 4, lines 26-44 of Pelz). However, Higgins teaches that PVDF (polyvinylidene fluoride) film is a type of polarized, polymeric piezoelectric material (col. 5, lines 39-60) suitable for sensing physiological parameters. Therefore, it would have been obvious to use PVDF as the sensor of Pelz, since Pelz teaches using a piezoelectric film, and Higgins teaches that PVDF is a suitable piezoelectric film.

Response to Amendment

The amendment filed 4/15/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material that is not supported by the original disclosure is as follows:

a processor for or a step of extracting signals due to cardiac activity of a patient by selectively omitting signals from sensors remote from a patient's extremities, as claimed in claims 135-138 (see claim 135) and 143-144 (see claim 143);

an apparatus having at least three sensors at at least three different parts of the patient's body and a processor that determines pulse wave velocity in response to the time difference between signals from at least three sensors, as claimed in claims 150, 154-158, 161, 164-174.

The applicants are required to cancel the new matter in the reply to this Office action.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The applicants argue that Pelz fails to teach or suggest the particular correlation approach describe by claims 107, 122, and 127. Claim 107 recites "processing the digital signals to extract signal associated with the physiology of the patient by correlating signals between sensors". Claim 122 recites, "correlating said digital signals to extract signals associated with the physiology of the patient". Claim 127 recites, "processing the digital signals to extract signals associated with at least one selected physiological parameter of the patient". Pelz processes digital signals by correlating the signal from each sensor with each other (col. 5, line 60-col. 6, line 37) in order to extract the physiological signal, which in this case is a pulse wave propagation rate. Therefore, Pelz indeed teaches the "particular correlation approach" as claimed by claims 107, 122, and 127.

Allowable Subject Matter

Claims 56 and 187 are allowed. The allowability of claim 56 was addressed in the previous Office action, filed 11/5/03. The allowable subject matter of claim 56 was incorporated into the body of claim 187.

Claims 98, 119, 142, and 146 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is an examiner's statement of reasons for allowance:

Regarding claims 98 and 119, the prior art fails to teach or fairly suggest a method or apparatus for passively monitoring the physiology of a patient comprising the combination of a step of or processor for correlating the signals of a first and a second sensor to extract signals associated with the physiology of a patient with the steps of or processor for calculating an energy spectrum and extracting signals associated with the physiology of a patient by identifying peaks in the energy spectrum corresponding to physiology parameters of the patient.

Regarding claim 142 and 146, the prior art of record fails to teach or fairly suggest an apparatus or method for passively monitoring the physiology of a patient comprising a processor or step of communicating with a converter for extracting signals from a plurality of sensors, which sense mechanical activity of a patient, by selectively comparing the signals from different locations on a patient's body, wherein the processor also transforms or the method further comprises a step of transforming the signals into frequency signals including respiration and heart rate harmonics and

differentiates the respiration and heart rate harmonics by selectively comparing signals from the different locations on the body.

Regarding claims 148 and 152, the prior art of record fails to teach or fairly suggest an apparatus for passively monitoring the physiology of a patient comprising at least two sensors, each sensor comprising a polarized polymer film with piezoelectric properties for sensing physiological parameters of the patient at different parts of the patient's body and wherein the at least two sensors comprise a first sensor disposed at a first location along a patient supporting surface and a second sensor disposed at a second location along the patient supporting surface remote from the first location, a converter communicating with the sensors for converting the sensed parameters into digital signals, and a processor communicating with the converter for determining a time difference between corresponding signals from the sensor, determining either a pulse wave velocity or pulse wave travel time from that time difference, and converting the pulse wave velocity or pulse wave travel time into signals corresponding to blood pressure data.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (703) 605-0422. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner
Art Unit 3736

MARY BETH JONES
ACTING SUPERVISORY PATENT EXAMINER